



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

FEB - 8 2007

Ms. Lisa Gorman  
Quality Control Coordinator 49 7 FEB 13 14:35  
Food Science Corporation  
20 New England Drive  
Essex Junction, Vermont 05453

Dear Ms. Gorman:

This is in response to your letter of January 22, 2007 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for the product Davinci Laboratories of Vermont Kids DHA Plus and Foodscience of Vermont Kids DHA Plus.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet (21 U.S.C. 321(ff)(2)(B)). The products identified above, notwithstanding your assertion that they are dietary supplements, appear to be represented for use as conventional foods (i.e., "Kids DHA Plus is a delicious orange-flavored beverage...."). Therefore, in that it appears to be represented for use as a conventional food (i.e., a beverage), it does not appear to be a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

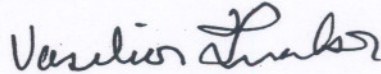
Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. Use of a food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market this product as a conventional food and you have any questions about the status of any of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

97S 0163 LET 927

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Please contact us if you require further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, New England District Compliance, HFR-NE240





FOODSCIENCE  
OF VERMONT®

U.S. ANIMAL  
OF VERMONT

VETRI-SCIENCE®  
LABORATORIES OF VERMONT

DaVinci Laboratories  
OF VERMONT



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pet naturals®  
of Vermont

January 22, 2007

Food and Drug Administration  
Office of Nutritional Products, Labeling and Dietary Supplements  
(HFS-810)  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Pkwy  
College Park, MD 20740

Dear Sir Madam:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. 343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that FoodScience Corporation and 20 New England Drive, Essex Junction, VT 05453 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM(S):

"A Dietary Supplement to Support Brain and Cognitive Functions"

"Kids DHA Plus is a delicious orange-flavored beverage designed to provide children with the necessary nutritional support for cognitive function. Complete with added minerals, probiotics and patented N,N Dimethylglycine. Kids DHA Plus provides more nutrients for brain health than any other DHA product on the market today."

NAME OF INGREDIENT(S) THAT IS SUBJECT OF CLAIM

Vitamin C  
Riboflavin  
Calcium (as Calcium Citrate)  
Magnesium (as Mg Citrate)  
Zinc (as Zinc Citrate)  
DHA  
Dimethylglycine HCl  
Lactobacillus Acidophilus

NAME OF SUPPLEMENT (INCLUDING BRAND NAME)

DaVinci Laboratories of Vermont: Kids DHA Plus  
Foodscience of Vermont: Kids DHA Plus

The undersigned certifies that the information contained in this notice is complete and accurate and that FoodScience Corporation has substantiation that the statements are truthful and not misleading.

Sincerely,

Lisa Gorman  
Quality Control Coordinator

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